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January 17, 2022

VIA CM/ECF

Honorable Thomas I. Vanaskie, Special Master
Stevens & Lee, P.C.
1500 Market Street, East Tower, 18th Floor
Philadelphia, Pennsylvania 19103

Re: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*,
No. 1:19-md-02875-RBK (D.N.J.)

Dear Judge Vanaskie:

Plaintiffs respectfully submit this letter in advance of the January 18, 2022 status conference.

1. Update on ZHP's Confidentiality Designations

The Parties have continued to meet and confer regarding the confidentiality designations for ECF 826, 967, 1189, and 1250 as well as the transcripts of John Iozzia's and Lijie Wang's depositions. Plaintiffs have provided ZHP with their position on ECF 826, 967, 1189, and 1250 as well as John Iozzia's deposition transcript. They intend to provide their response to ZHP's revised designations of Lijie Wang's deposition transcript shortly. ZHP is also reconsidering its designation of 45 documents at issue. The Parties plan to have a telephonic meet and confer

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regarding these designations shortly after exchanging their positions regarding the remaining documents in writing.

On December 21, 2021, the Court directed the Parties to “include oral argument on the confidentiality designations of the fourteen (14) documents referenced in part (g) above and identified by ECF Number and Exhibit Number in section VII of the ZHP Parties’ status report (ECF No. 1823).” ([ECF 1826](#)). ZHP asked to extend that deadline to the second conference held this month, and the Court granted that request. However, ZHP has not served an affidavit based on personal knowledge supporting its position that these fourteen documents are confidential, as required by Local Rule 5.3(c)(3). The Court has previously emphasized the legal requirement under the Local Rules that an affidavit based on personal knowledge is a necessary part of any request to seal documents. ([12/09/2020 Tr., 10:1-22](#) (stating, “I expect Torrent to produce with that in-camera inspection, a supporting affidavit, and then I will determine whether or not the confidentiality designation is appropriate or not. I've written a lot on this issue, an affidavit from an attorney is insufficient. An attorney doesn't have firsthand knowledge of what's required under the order, the discovery order that the Court entered. So if you submit a supporting affidavit signed by an attorney, I expect that your application will be denied quickly, but I would expect you to submit an affidavit from an appropriate knowledgeable person from your clients who has personal knowledge of the issues to support the claim that under the requirements in the discovery confidentiality order, it meets those criteria.”). As the Court knows, this type of affidavit is required for any motion to seal. ([ECF 1871](#) (analyzing the Declaration of Dr. Min Li)). Having failed to provide the requisite affidavit supporting its designations, ZHP cannot maintain the confidentiality of the fourteen documents at issue. Plaintiffs ask the Court to enter an order confirming that these documents are no longer confidential. *See In re Caterpillar Inc., C13 and*

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C15 Engine Prods. Liab. Litig., MDL No. 2540, 2015 WL 12830520, at *3 (D.N.J. Jan. 29, 2015)

(denying motion to seal that was supported by an affidavit without personal knowledge) (Ex. 1);

Schatz-Bernstein v. Keystone Food Prods., Inc., No. 08-3079-RMB-JS., 2009 WL 1044946, at

*2 (D.N.J. Apr. 17, 2009) (same) (Ex. 2).

To the extent that the Court nevertheless wishes to reach the merits, Plaintiffs briefly summarize the legal standard and the reasons why the documents do not warrant sealing. “Once a document becomes a judicial record, a presumption of access attaches.” ([ECF 1871](#), ¶ 13 (quoting *In re Avandia Mktg., Sales Practices and Products Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019)). “The party seeking to overcome the presumption of access bears the burden of showing ‘that the interest in secrecy outweighs the presumption.’ The movant must show ‘that the material is the kind of information that courts will protect and that disclosure will work a **clearly defined and serious injury to the party seeking disclosure.**’” (*Id.* at ¶ 14 (quoting *In re Avandia Mktg., Sales Practices and Products Liab. Litig.*, 484 F. Supp. 3d 249, 259 (E.D. Pa. 2020)) (emphasis added). This means:

To overcome that strong presumption, the District Court must articulate the compelling, countervailing interests to be protected, make specific findings on the record concerning the effects of disclosure, and provide an opportunity for interested third parties to be heard. In delineating the injury to be prevented, specificity is essential. *Broad allegations of harm, bereft of specific examples or articulated reasoning, are insufficient.* Careful factfinding and balancing of competing interests is required before the strong presumption of openness can be overcome by the secrecy interests of private litigants. To that end, the District Court must conduct a document-by-document review of the contents of the challenged documents.

(*Id.* at ¶ 15 (quoting *Avandia*, 924 F.3d at 672-73)). “An order sealing a judicial record must be based on ‘**current evidence to show how public dissemination of the pertinent materials now**

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would cause the competitive harm' ...” (*Id.* at ¶ 23 (quoting *Leucadia, Inc. v. Applied Extrusion Techs., Inc.*, 998 F.2d 157, 167 (3d Cir. 1993)) (emphasis added). Importantly, “[c]oncern about a company's public image, embarrassment, or reputational injury, without more, is insufficient to rebut the presumption of public access.” (*Id.* at ¶ 16 (quoting *Avandia*, 924 F.3d at 676)). Moreover, the public's right to access court records is “*particularly important in a case such as this one, which implicates the public's trust in a well-known and (formerly) widely-used drug.*” (*Id.* at ¶ 17 (quoting *Avandia*, 924 F.3d at 677)).

As already noted, without providing an affidavit supporting any “clearly defined and serious injury,” ZHP has not met its burden on this motion for any of the fourteen documents. (*Id.* at ¶ 14 (quoting *Avandia*, 484 F. Supp. 3d at 259)). Nevertheless, Plaintiffs provide the following analysis anticipating ZHP's arguments based on the Parties' informal meet and confer.

1. ZHP02500007 (ECF No. 826, Ex. 49): This document is [REDACTED]

[REDACTED]

[REDACTED] . (ZHP02500009). [REDACTED]

[REDACTED] . (*Id.*). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]
[REDACTED]
(ZHP02500010 (emphasis added)). Plaintiffs note that the [REDACTED] final version [REDACTED]

contains the same substantive provisions.

There is strong authority to unseal this document. Local Civil Rule 5.3(d) states that “[a]ny settlement agreement filed with the Court or incorporated into an order shall, absent an appropriate showing under federal law, be deemed a public record and available for public review.” Settlement discussions are equally subject to public review once becoming court records. *Schatz-Bernstein*, 2009 WL 1044946, at *2-3 (denying the motion to seal, explaining: “The Court is mindful of Fed.R.Evid. 408 which generally prohibits the introduction of evidence regarding parties’ settlement negotiations. However, the admissibility of a document at trial is not determinative regarding whether the document should be sealed. See *Republic of the Philippines v. Westinghouse Electric Corporation*, 139 F.R.D. 50, 58 (D.N.J. 1991) (the right of public access to court records is not limited to evidence admitted at trial).”) (Ex. 2). Moreover, [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]. ([ECF 1871](#), ¶ 17 (quoting *Avandia*, 924 F.3d at 677)). As a result, this Court should deny ZHP’s request to seal this document.

¹ Plaintiffs hereby incorporate their prior discussion of the insignificance of “confidentiality” provisions to a court’s decision on whether to seal a document. ([ECF 1736](#), p. 9-11).

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2. CHARLESWANG000026 (ECF No. 1189, Ex. X): This email contains very limited information, and nothing raises an interest overcoming the public's right to access the email as a court record. Plaintiffs note that they do not have a written translation of this document, but ZHP bears the burden on this issue, so if it declines to provide one to establish the need for sealing, then the Court should deny the request for sealing. ([ECF 1871](#), ¶ 14 (quoting *Avandia*, 484 F. Supp. 3d at 259)).

3. ZHP02324745 (ECF No. 1189, Ex. CC): This document is the final GMP inspection report from the European Medical Agency (EMA) and European Directorate for the Quality of Medicines & HealthCare (EDQM), [REDACTED]

(ZHP02324737). [REDACTED]

(*Id.*). Unlike many of the documents attached to ECF 1189, ZHP has not offered to make this document public while redacting certain portions. This is puzzling since this document is quite similar to many public documents, and regulatory findings, and is presumably public as well since the contents are in the public sphere through many other sources. There is nothing about this information that merits confidentiality. ZHP's interest in hiding the details of its misconduct cannot overcome that interest. ([ECF 1871](#), ¶ 16 (quoting *Avandia*, 924 F.3d at 676-77)).

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4. ZHP01662332 (ECF No. 1250, Ex. 1): This document is a limited excerpt from ZHP's 2007 Drug Master File for valsartan. It does not contain any proprietary information that could benefit competitors, and it shows Baohua Chen's central role within the ZHP Organization, which is also a matter of public record, including in the Court's orders regarding the custodial file and deposition of Mr. Chen. There is no countervailing interest that would outweigh the presumption of the public's right to access this document. ([ECF 1871](#), ¶ 23 (quoting *Leucadia*, 998 F.2d at 167)).

5. ZHP01633850 (ECF No. 1250, Ex. 2): This document is a limited excerpt from ZHP's 2011 Drug Master File for valsartan. It does not contain any proprietary information that could benefit competitors, and it shows Baohua Chen's central role within the ZHP Organization, which is a matter of public record. No countervailing interest would outweigh the presumption of the public's right to access this document. ([ECF 1871](#), ¶ 23 (quoting *Leucadia*, 998 F.2d at 167)).

6. ZHP01458548 (ECF No. 1250, Ex. 3): This document is a limited excerpt from ZHP's 2012 Drug Master File for valsartan. It does not contain any proprietary information that could benefit competitors, and it shows Baohua Chen's central role within the ZHP Organization, which is a matter of public record. No countervailing interest outweighs the presumption of the public's right to access this document. ([ECF 1871](#), ¶ 23 (quoting *Leucadia*, 998 F.2d at 167)).

7. ZHP02579748 (ECF No. 1250, Ex. 5): This memo is a routine business communication from 2013 concerning the sale of valsartan made using a discontinued manufacturing process that yielded valsartan contaminated with nitrosamines. It would not be of any use to ZHP's competitors, as nobody would or could use that process, which is a matter of public record, ever again. There is no countervailing interest that would outweigh the presumption of the public's right to access this document. ([ECF 1871](#), ¶ 23 (quoting *Leucadia*, 998 F.2d at 167)); *see also In*

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re Valsartan N-Nitrosodimethylamine (NDMA), Losartan, and Irbesartan Prods. Liab. Litig., 512

F. Supp. 3d 546, 555 (D.N.J. 2021) (denying Torrent's request to seal five documents because “[a]t bottom, Torrent's emails involve what appears to be routine business communications”). Plaintiffs also note that they do not have a written translation of this document, but ZHP bears the burden on this issue, so if it declines to provide one to establish the need for sealing, then the Court should deny the request for sealing. ([ECF 1871](#), ¶ 14 (quoting *Avandia*, 484 F. Supp. 3d at 259)).

8. SOLCO00012089 (ECF No. 1250, Ex. 6): This email is a routine business communication from 2017 concerning the sale of valsartan made using a discontinued manufacturing process that yielded valsartan contaminated with nitrosamines. It would not be of any use to ZHP's competitors, as nobody would or could use that process, which is a matter of public record, ever again. There is no countervailing interest that would outweigh the presumption of the public's right to access this document. ([ECF 1871](#), ¶ 23 (quoting *Leucadia*, 998 F.2d at 167)); *see also Valsartan*, 512 F. Supp. 3d at 555 (denying Torrent's request seal five documents because “[a]t bottom, Torrent's emails involve what appears to be routine business communications”)).

9. SOLCO00189499 (ECF No. 1250, Ex. 7): This email is a routine business communication from 2016 concerning the sale of valsartan made using a discontinued manufacturing process that yielded valsartan contaminated with nitrosamines. It would not be of any use to ZHP's competitors, as nobody would or could use that process, which is a matter of public record, ever again. No countervailing interest would outweigh the presumption of the public's right to access this document. ([ECF 1871](#), ¶ 23 (quoting *Leucadia*, 998 F.2d at 167)); *see also Valsartan*, 512 F. Supp. 3d at 555 (denying Torrent's request seal five documents because “[a]t bottom, Torrent's emails involve what appears to be routine business communications”)).

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10. SOLCO00025179 (ECF No. 1250, Ex. 8): This email is a routine business communication from 2017 concerning the sale of valsartan made using a discontinued manufacturing process that yielded valsartan contaminated with nitrosamines. It would not be of any use to ZHP's competitors as nobody would or could use that process, which is a matter of public record, ever again. No countervailing interest outweighs the presumption of the public's right to access this document. ([ECF 1871](#), ¶ 23 (quoting *Leucadia*, 998 F.2d at 167)); *see also Valsartan*, 512 F. Supp. 3d at 555 (denying Torrent's request seal five documents because “[a]t bottom, Torrent's emails involve what appears to be routine business communications”)).

11. ZHP02385482 (ECF No. 1250, Ex. 16): This is a routine business communication, discussing ZHP's cynical attempt to exploit the nitrosamine contamination to its benefit shortly after its disclosure to regulatory authorities as well as Baohua Chen's central involvement within the ZHP Organization. The time for exploiting this issue has long passed, thus there no current competitive harm can be suggested. There is no countervailing interest that would outweigh the presumption of the public's right to access this document. ([ECF 1871](#), ¶ 23 (quoting *Leucadia*, 998 F.2d at 167)); *see also Valsartan*, 512 F. Supp. 3d at 555 (denying Torrent's request seal five documents because “[a]t bottom, Torrent's emails involve what appears to be routine business communications”)).

12. ZHP01423197 (ECF No. 1250, Ex. 17): This is a draft letter to the EDQM regulatory authority explaining ZHP's response to the “discovery” of the nitrosamine contamination of its sartans. This is not proprietary, and disclosure could not cause any current harm. ZHP has stated publicly its version of what occurred anyway, so this is not reasonably described as confidential. The public also has a strong interest in understanding this response. ([ECF 1871](#), ¶ 16 (quoting *Avandia*, 924 F.3d at 676-77)). And the Court has already ruled that a draft document does not in

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and of itself warrant sealing. ([ECF 1269](#), p. 6). The Court should similarly deny ZHP's request to seal this document.

13. **ZHP01224767 (ECF No. 1250, Ex. 20):** This is a routine business communication discussing ZHP’s response to the “discovery” of the nitrosamine contamination, which is it described as “[REDACTED].” (ZHP01224788). It also establishes Baohua Chen’s key role in directing that response. (*Id.*) There is nothing currently proprietary or that would cause significant to harm if not sealed. The Court should not seal this document. ([ECF 1871](#), ¶ 16 (quoting *Avandia*, 924 F.3d at 676-77)); *see also Valsartan*, 512 F. Supp. 3d at 555 (denying Torrent’s request seal five documents because “[a]t bottom, Torrent’s emails involve what appears to be routine business communications,” “[a]lbeit, the emails were prepared in response to what appears to be an unprecedented situation”).

14. ZHP02666849 (ECF No. 1250, Ex. 28): This memo is a routine business communication discussing ZHP's response to the EDQM regulatory authority. It states that [REDACTED]

.” (ZHP02666849). There is nothing of any current import to this document that would merit sealing, especially as the requirement to meet the defined levels was public knowledge, and ZHP publicly agreed to comply. The public also has a strong interest in understanding that [REDACTED]

Hiding this fact is not a justification for sealing this document. ([ECF 1871](#), ¶ 16 (quoting *Avandia*, 924 F.3d at 676-77)); *see also Valsartan*, 512 F. Supp. 3d at 555 (denying Torrent’s request seal five documents because

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“[a]t bottom, Torrent’s emails involve what appears to be routine business communications,” “[a]lbeit, the emails were prepared in response to what appears to be an unprecedented situation.”).

2. Update on Special Master Order 56 Submissions

As ordered, the Parties will submit their updates on this issue by noon tomorrow.

3. Dismissal of Rite Aid and Walgreens from Master Medical Monitoring Complaint

Plaintiffs agree that Rite Aid and Walgreens should be dismissed from the medical monitoring master complaint, and will work with those defendants to effect that dismissal promptly.

4. Deposition Logistics for Plaintiffs’ Class Certification Experts

As of the filing of this letter,² the Class Plaintiffs have two class certification experts (Laura Craft, and Dr. Ron Najafi) who wish to have their deposition conducted entirely remotely, due to the current COVID situation and their own personal circumstance. (See Pls’ Email at Ex. A (indicating that Ms. Craft wished to proceed remotely, as she is currently living with a newborn infant grandchild)). As soon as Plaintiffs learned of these requests, Plaintiffs promptly informed Defendants of this request. (*Id.*).

Despite this being the wish of the experts (and the fact that Plaintiffs’ Counsel agreed that they, too, would proceed remotely), Defendants stated that they would “revisit [the question of remote depositions] closer in time to the deposition.” (*Id.*). As of this CMC, Defendants have not agreed to the request.

² Plaintiffs believe the balance of their Class Certification expert depositions will proceed in-person, with the limitations on attendees as previously set by the Court. However, Plaintiffs reserve their rights in the event the personal circumstances and preferences of the expert witnesses may require a remote deposition.

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Plaintiffs understood from previous CMCs that should a witness have a strong preference for a remote deposition, the Court would permit such depositions to proceed remotely (especially in situations where the defending attorney agreed to proceed remotely). Indeed, this was the method in which Plaintiffs took the depositions of over fifty of Defendants' 30(b)(6) witnesses. Plaintiffs request that the Court order that if a class certification expert wishes to proceed with a fully remote deposition, the Parties must honor that request without having to make a further application to the Court.

Thank you for your courtesies and consideration.

Respectfully,



ADAM M. SLATER

cc: All Counsel (via CM/ECF)